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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,909	11/17/2000	Ronald D. Flannagan	35718/204664	5613

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EXAMINER
HOLBROOK, PAMELA G

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,909	FLANNAGAN ET AL.RRRRRR	
	Examiner	Art Unit	
	Pamela G Holbrook	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4-6,9 and 19-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,8,10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-25 are pending in the case. In Paper No. 9 filed January 3, 2002, Applicant elected with traverse Group I drawn to nucleic acid, vectors and host cells (claims 1-3, 7,8 and 10-18 directed to SEQ ID NO: 1 encoding SEQ ID NO: 2). Therefore, claims 1-3, 7,8 and 10-18 will be examined in so far as they read on the elected species SEQ ID NO: 1. Claims 4-6, 9 and 19-25 are withdrawn as drawn to the non-elected species.

2. The field of the invention relates to the isolation and characterization of nucleic acid and polypeptides for a novel *Bt* toxin receptor useful in developing new insecticides.

Claim Objections

3. Claims 7 and 8 are objected to for depending from a non-elected claim, claim 5.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 16-18 are rejected under the first paragraph of 35 U.S.C. 112, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The

specification describes a sequence consisting of SEQ ID NO: 1 that is shown to encode a protein that has properties of a *Bt* toxin receptor. However, the claims as written encompass variants and fragments of SEQ ID NO: 1. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, biological activity of a single identified polypeptide encoded by sequence SEQ ID NO: 1. The specification further sets forth a proposed region corresponding to the *Bt* toxin binding site for the genus, yet there is no correlation or nexus provided between possession of this structural feature and the encompassed functional features of SEQ ID NO: 1 such that it is clearly conveyed that possession of any polypeptide having this structural region in common would possess *Bt* toxin receptor biological activity.

Claims 1-3 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising SEQ ID NO: 1, does not reasonably provide enablement for polypeptides consisting of fragments or variants thereof. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to polypeptides consisting of fragments or variants of SEQ ID NO: 1. The specification discloses a single polypeptide of SEQ ID NO: 1 possessing specific functions of a *Bt* toxin receptor namely the ability to mediate insect cell toxicity in response to the *Bt* toxin, Cry1Ab (page 37, line 30). There is no disclosure of regions or specific amino acids within the SEQ ID NO: 1 protein where amino acid substitutions would be tolerated without functional change to the protein and regions where they would not be tolerated. The amino acid sequence of a protein determines its structure but this alone is not sufficient to determine its functional properties and proteins can gain and loose function during evolution (Trends in Biothechnology (2000) 18(1); 34-39). Furthermore, cell responses and biological activities in the broad context are known in the art to be transduced by cell surface receptors through intricate signaling complexes and cascades involving various ancillary proteins, effectors, second messengers and/or changes in intracellular ion concentration, redox potential or pH. The specification does not disclose properties of the protein that predict an ability to manifest changes in any known signaling cascade nor does it disclose that the transfected polypeptide is capable of effecting such changes so as transduce insect cell toxicity.

Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for *Bt* toxin receptor biological activity or to reasonably predict whether the broadly claimed fragments or variants of SEQ ID NO: 1 indeed function as receptors, would prevent one of ordinary skill in the art from determining whether such modifications are commensurate with *Bt* toxin receptor biological activity without undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7- 8 and 10-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 10-11, 14 and 16 recite a "cell of interest". A "cell of interest" is defined in the specification (page 6, line 1-20) as any cell in which expression of the polypeptides of the invention is desired. Thus in the recitation of "cell of interest" claims 7, 10-11, 14 and 16 do not particularly point out and distinctly define the metes and bounds of the subject matter. Claims 8, 12-13, 15 and 17-18 are also rejected under 35 U.S.C. 112, second paragraph, for depending from an indefinite claim, claim 7, claim 10, claim 14 and claim 16 respectively.

Claims 2 and 3 recite the limitation "wherein said toxin ". There is insufficient antecedent basis for this limitation in the claim.

6. The closest prior art to the claimed invention is contained in US Patent # 5693391which teaches a *Bt* toxin receptor 35.6 % homologous to the instant *Bt* toxin receptor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela Holbrook whose telephone number is (703) 306-3221, Mon.- Fri. 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [gary.kunz@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 8, 2002

Gary L. Kunz

GARY L. KUNZ
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